

PRESCRIPTION SIGNATURE OPTIONS

June 27, 2008

The Code of Maryland Regulations (COMAR) cited in the chart are set forth below

Definitions:

1. **Manually written signature** – a pen to paper signature by the *an authorized prescriber* composed at the time the prescription is completed.
2. **Non encoded electronic signature** – any scanned, preprinted, *handwritten on LED* or inserted facsimile of the *authorized prescriber* signature not composed at the time the original prescription is completed.
3. **Acceptable Encoded Electronic Signature must be:**
 - a) Processed by a commercial intermediary, which guarantees the confidentiality and security of the transmission process in a manner approved by the Board; and
 - b) Transmitted directly to the pharmacy computer (not hard copy).

	Type of Prescription	CII	CIII – CV	Non-CDS
1.	Traditional Prescription	PERMITTED <i>Original</i> manually written signature, original required at pick-up COMAR 10.19.03.08	PERMITTED Requires <i>original</i> manually written signature, and requirements of COMAR 10.19.03.09A(1)	PERMITTED Requires <i>original</i> manually written signature
2a.	Call-in Prescription Emergency	(A) PERMITTED Reduce to writing; Written Rx must be sent to pharmacist within 7 days pursuant to COMAR 10.19.03.08A(4(d))	(A) PERMITTED Reduce to writing and contains information required in COMAR 10.19.03.07D	(A) PERMITTED Reduce to writing and contains information required in COMAR 10.34.20.02
2b.	Call-in Prescription Routine	(B) NOT PERMITTED COMAR 10.19.03.08	(B) PERMITTED Reduce to writing and contains information required in COMAR 10.19.03.07D	(B) PERMITTED Reduce to writing and contains information required in COMAR 10.34.20.02
3.	Faxed Prescription	PERMITTED Using traditional prescription pad – <i>original</i> manually written signature,	PERMITTED <i>Original</i> manually written signature, COMAR 10.19.03.09A(1)	PERMITTED <i>Original</i> manually written signature. Comply w/ COMAR 10.34.20

	Type of Prescription	CII	CIII – CV	Non-CDS
		original required at pick-up COMAR 10.19.03.08		and all elements required of a Rx in Health-General, 21-220
4.	Prescription printed at office by computer and hand carried by patient or agent of patient	PERMITTED <i>Original</i> manually written signature, COMAR 10.19.03.08	PERMITTED <i>Original</i> manually written signature, COMAR 10.19.03.09A(1)	PERMITTED <i>Original</i> manually written signature, Comply w/ COMAR 10.34.20.02
5.	Prescription printed at office by computer and faxed or scanned	PERMITTED <i>Original</i> manually written signature, original required at pick-up 10.19.03.08	PERMITTED <i>Original</i> manually written signature, 10.19.03.09A(1)	PERMITTED <i>Original</i> manually written signature and Comply w/ 10.34.20
6.	Prescription produced by computer at office and no paper document printed at office, then e-mailed or faxed without ORIGINAL MANUALLY WRITTEN SIGNATURE	NOT PERMITTED COMAR 10.19.03.08	NOT PERMITTED COMAR 10.19.03.09 unless verbally verified	NOT PERMITTED Unless verified verbally. Comply w/ COMAR 10.34.20
7.	Prescription produced by computer at office and no paper document printed at office, then e-mailed or faxed with pre-scanned signature	NOT PERMITTED COMAR 10.19.03.08	NOT PERMITTED Unless verbal verification COMAR 10.19.03.09A(1)	PERMITTED Use professional judgment and Comply w/ COMAR 10.34.20
8.	Electronic Transmission using software with encoded electronic or	NOT PERMITTED COMAR 10.19.03.08	NOT PERMITTED Unless verbal verification COMAR	PERMITTED Comply w/ COMAR 10.34.20 Permitted if processed in a

	Type of Prescription	CII	CIII – CV	Non-CDS
	digital signature		10.19.03.09	manner approved by the Board.
9.	Prescription transmitted on a hand held device with encoded electronic or digital signature	NOT PERMITTED COMAR 10.19.03.08	NOT PERMITTED Unless verbal verification 10.19.03.09A(1)	PERMITTED Comply w/ COMAR 10.34.20 Permitted if processed in a manner approved by the Board.
10.	Prescription transmitted on a hand held device WITHOUT ENCODED ELECTRONIC OR DIGITAL SIGNATURE	NOT PERMITTED COMAR 10.19.03.08	NOT PERMITTED COMAR 10.19.03.09	NOT PERMITTED Unless verified verbally. Comply w/ COMAR 10.34.20

This chart should be considered a general guide for determining the validity of a prescriber's signature on prescriptions. Please contact the Board of Pharmacy for specific questions and concerns at mdbop@dhmh.state.md.us or (410) 764-4794.

The following regulations do not include the complete COMAR Chapters referenced. Please refer to the entire COMAR Chapters for additional information and requirements.

10.19.03.07

D. Manner of Issuance of Prescriptions (21 CFR §1306.05).

(1) All prescriptions for controlled dangerous substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address, and registration number of the practitioner. A practitioner may sign a prescription in the same manner as the practitioner would sign a check or legal document (for example, J.H. Smith or John H. Smith). When an oral order is not permitted, prescriptions shall be written with ink, indelible pencil, typewriter, or computer and shall be manually signed by the practitioner. The prescriptions may be prepared by a secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations. A corresponding liability rests upon the pharmacist who fills a prescription not prepared in the form prescribed by these regulations.

10.19.03.08

.08 Controlled Substances Listed in Schedule II.

A. Requirement of Prescription—Schedule II (21 CFR §1306.11).

(1) A pharmacist may dispense directly a controlled dangerous substance listed in Schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, only pursuant to a written prescription signed by the prescribing individual practitioner, except as provided in §A(4) of this regulation. Except as noted in §A(5)–(7) of this regulation, a prescription for a Schedule II controlled substance may be transmitted by the practitioner or the practitioner's agent to a pharmacy by facsimile equipment, if the original written, signed prescription is presented to the pharmacist for review before the actual dispensing of a controlled substance.

(4) In the case of an emergency situation, as cited in 21 CFR §1306.11(d), a pharmacist may dispense a controlled dangerous substance listed in Schedule II upon receiving oral authorization of a prescribing individual practitioner, if all of the following requirements are met:

(a) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period (dispensing beyond the emergency period must be pursuant to a written prescription signed by the prescribing individual practitioner);

(b) The prescription shall be immediately reduced to writing by the pharmacist and shall contain all information required in Regulation .07 of this chapter, except for the signature of the prescribing individual practitioner;

(c) If the prescribing individual practitioner is not known to the pharmacist, the pharmacist shall make a reasonable effort to determine that the oral authorization came from a registered individual practitioner, which may include a call back to the prescribing individual practitioner using the prescribing individual practitioner's telephone number as listed in the telephone directory or other good faith efforts to insure the individual practitioner's identity;

(d) Within 7 days after authorizing an emergency oral prescription, the prescribing individual practitioner shall have a written prescription for the emergency quantity prescribed delivered to the dispensing pharmacist. In addition to conforming to the requirements of Regulation .07 of this chapter, the prescription shall have written on its face "Authorization for Emergency Dispensing", and the date of the oral order. The written prescription may be delivered to the pharmacist in person or by mail, but if it is delivered by mail, it shall be postmarked within the 7-day period. Upon receipt, the dispensing pharmacist shall attach this prescription to the oral emergency prescription which had earlier been reduced to writing. The pharmacist shall notify in writing the Department of Health and Mental Hygiene if the prescribing individual practitioner fails to deliver a written prescription to the pharmacist; failure of the pharmacist to do so shall void the authority conferred by this section to dispense without a written prescription of a prescribing individual practitioner.

D. Labeling of Substances (21 CFR §1306.14).

(1) The pharmacist filling a written or emergency oral prescription for a controlled dangerous substance listed in Schedule II shall affix to the package a label showing the date of filling, the pharmacy name and address, the serial number of the prescription, the name of the patient, the name of the prescribing practitioner, and directions for use and cautionary statements, if any, contained in this prescription or required by law. It is further provided that the label of a drug listed in Schedules II, III, IV, and V of Criminal Law Article, §§5-403–5-406, Annotated Code of Maryland, shall, when dispensed to or for a patient, contain a clear, concise warning that it is a crime to transfer the drug to any person other than the patient. When the size of the label space requires a reduction in type, the reduction shall be made to a size no smaller than necessary and in no event to a size smaller than six-point type.

(2) The requirements of §D(1) of this regulation, do not apply when a controlled dangerous substance listed in Schedule II is prescribed for administration to an ultimate user who is institutionalized, provided that:

(a) Not more than a 7-day supply of the controlled dangerous substance listed in Schedule II is dispensed at one time;

(b) The controlled dangerous substance listed in Schedule II is not listed in the possession of the ultimate user before the administration;

(c) The institution maintains appropriate safeguards and records regarding the proper administration, control, dispensing, and storage of the controlled dangerous substance listed in Schedule II; and

10.19.03.09

A. Requirement of Prescriptions Listed in Schedules III, IV, and V (21 CFR §1306.21).

(1) A pharmacist may dispense directly a controlled dangerous substance listed in Schedules III, IV, or V, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, or State Law, only pursuant to either a written prescription signed by a prescribing individual practitioner or a facsimile received by facsimile equipment of a written, signed prescription transmitted by the practitioner or the practitioner's agent to the pharmacy or pursuant to an oral

prescription made by a prescribing individual practitioner and immediately reduced to writing by the pharmacist containing all information required in Regulation .07 of this chapter, except the signature of the prescribing individual practitioner.

10.34.20.01

.01 Scope.

A. This chapter applies to the conveyance or transmission of prescription orders from authorized prescribers to pharmacies in the State.

10.34.20.02

.02 Requirements for Prescription Validity.

A valid prescription shall be:

A. Valid in the professional judgment of the pharmacist responsible for filling the prescription;

B. Conveyed in a form which:

(1) Contains the signature of the prescriber,

(2) Contains an alternative method of communication acceptable for commerce in the State, which indicates that the authorized prescriber has personally originated or approved the prescription,

(3) Provides for audio or visual interaction between the authorized prescriber or the agent of the authorized prescriber who is under the direct supervision of the authorized prescriber and the pharmacist, or

(4) Is processed by a commercial intermediary, which guarantees the confidentiality and security of the transmission process in a manner approved by the Board; and

C. Conveyed in a manner which:

(1) Ensures that the prescription electronically transmitted to the pharmacy contains no alterations by any intervening parties,

(2) Ensures that the prescription electronically transmitted to the pharmacy contains the same exact information it contained when originated by the authorized prescriber,

(3) Prevents unauthorized access and changes to the electronically transmitted prescription, and

(4) Does not interfere with a patient's freedom to choose a pharmacy.